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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/617,222 | 07/10/2003 | Susan A. Gregory | PHA 4145.4 (2918/3A) | 2378 |

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SENNIGER POWERS LEAVITT AND ROEDEL
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EXAMINER

KWON, BRIAN YONG S

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/617,222

Applicant(s)

GREGORY ET AL.

Examiner

Brian S. Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/06/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

8-0-0

DETAILED ACTION

Priority

1. According to the Bib Data Sheet of the instant application, this application, although filed on January 10, 2005, is a divisional application of US Serial No. 09/659,299, matured into US Patent No. 6,617, 345, filed 09/12/2000, which is a divisional application of US Serial No. 09/075,633, matured into US Patent No. 6,172,096, filed 05/11/1998, which is a continuation application of US Serial No. 08/600,580, filed 02/13/1996. While the combination of Cyclooxygenase-2-inhibitor, a leukotriene B4 receptor antagonist and an immunosuppressant was disclosed in the US Serial No. 09/659,299 and US Serial No. 09/075,633, this combination was not disclosed in the US Serial No. 08/600,580. Therefore, the present application has an effective filing date of 05/11/1998.

Claim Rejections - 35 USC § 112

2. Claims 2, 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 3 and 4 contain the trademark/trade name such as Dup-697, Taisho NS-398, Bayer Bay-x-1005, Ciba-Geigy CGS-25019C, Leo Denmark ETH-615, Lilly Ly-293111, Ono ONO-4057, Terumo TMK-688, Boehringer Ingleheim BI-RM-270, Lilly LY 213024, Lilly LY 264086, Lilly LY 292728, Ono ONO LB457, Pfizer 105696, Perdue Frederick PF 10042, Rhone-Poulenc Rorer RP 66153, SmithKline Beecham SB-201146, SmithKline Beecham SB-201993, SmithKline Beecham SB-209247, Searle SC-53228, Shinonogi S-2472, Searle SC-52798, Leo

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Denmark SR-2566, Tanabe T-757, Sumitamo SM 15178, American Home Products Way 121006, Warner-Lambert BPC-15 and Pfizer 105696. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe, for example 5-bromo-2-(4-fluorophenyl)-3-[4-(methylsulfonyl)phenyl]-thiophene (Dupont Dup-697) and (N-[2-(cyclohexyloxy)-4-nitrophenyl]-methanesulfonamide (Taisho NS-398) and, accordingly, the identification/description is indefinite.

3. Claims 5 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 13 contain no structure of the Formula I, and this consequently leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-9 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Isakson et al. (WO 96/41645).

The claims read on a combination comprising a COX-2 inhibitor, LTB₄ receptor antagonist and immunosuppressive drug, wherein said immunosuppressive drug is selected from the group consisting of antiproliferative agents, antiinflammatory-acting compound and inhibitors of leukocyte activation.

Isakson teaches a combination of COX-2 inhibitor (i.e., meloxicam, floculide, Merck MK-966, Taisho NS-398, compounds represented by the formula I, etc...) and a leukotriene B₄ receptor antagonist (i.e., Bayer Bay-x-1005, Ciba-Geigy CGS-25019C, ebselen, etc...) that is useful for the treatment of inflammation and inflammation-related disorders (i.e., arthritis).

As discussed above, the anti-inflammatory-acting compound is referred as the claimed immunosuppressive drug. Since the COX-2 inhibitor is generally considered as anti-inflammatory-acting compound in the art, both the immunosuppressive drug and the COX-2

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inhibitor could be the same agent. In other words, the claimed composition could only contain two active ingredients, COX-2 inhibitor and LTB4 receptor antagonist. Since there is no indication in the instant claims that the COX-2 inhibitor is completely different from the immunosuppressive drug, the referenced combination anticipates the claimed invention.

5. Claims 1-2, 5-8 and 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Weier et al. (US 568470).

Weier teaches the combination comprising COX-2- inhibitors and LTB4 inhibitors (column 3, lines 12-16). The referenced COX-2 inhibitors represented by the Formula II encompass “metes and bounds” the claimed COX-2 inhibitor represented by the Formula I of the instant application.

As discussed above, the anti-inflammatory-acting compound is referred as the claimed immunosuppressive drug. Since the COX-2 inhibitor is generally considered as anti-inflammatory-acting compound in the art, both the immunosuppressive drug and the COX-2 inhibitor could be the same agent. In other words, the claimed composition could only contain two active ingredients, COX-2 inhibitor and LTB4 receptor antagonist. Since there is no indication in the instant claims that the COX-2 inhibitor is completely different from the immunosuppressive drug, the referenced combination anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isakson et al. (WO 96/41645) in view of Pollock et al. (Drug Metabolism and Disposition, abstract, 1989, 17(6), 595-9).

The teaching of Isakson (WO 96/41645) has been discussed in above 35 USC 102(b) rejection.

Pollock is being supplied as a reference to demonstrate the routine knowledge in using cyclosporine A as known immunosuppressive agent that is useful for the treatment of arthritis.

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Above references in combination make clear that COX-2 inhibitor, LTB4 inhibitor and cyclosporine A have been individually used for the treatment of arthritis. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-13 are rejected under the judicially created doctrine of double patenting over claims 1-11 of U. S. Patent No. 6337329 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant invention overlaps with the patented claims.

Both of the instant application and the patent are directed to the combination of cyclooxygenase-2 inhibitor, a leukotriene B4 receptor antagonist and immunosuppressive drug, namely cyclosporine.

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8. Claims 1-9 and 12-13 are rejected under the judicially created doctrine of double patenting over claims 1-8 of U. S. Patent No. 6136839 A.

Although the conflicting claims are not identical, they are not patentably distinct from each other. As discussed above, the anti-inflammatory-acting compound is referred as the claimed immunosuppressive drug. Since the COX-2 inhibitor is generally considered as anti-inflammatory-acting compound in the art, both the immunosuppressive drug and the COX-2 inhibitor could be the same agent. In other words, the claimed composition could only contain two active ingredients, COX-2 inhibitor and LTB₄ receptor antagonist. Since there is no indication in the instant claims that the COX-2 inhibitor is completely different from the immunosuppressive drug, the referenced combination makes obvious the claimed invention.

In looking in continuity data, it is noted that applicant has numerous issued patent and pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s). For example, US 5700816 and 6342510 to be same or similar subject matter(s).

Conclusion

9. No Claim is allowed.

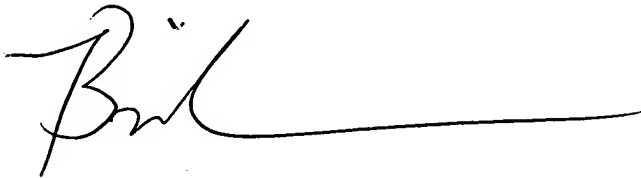
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

A handwritten signature in black ink, appearing to read 'B. Kwon', followed by a long horizontal line extending to the right.